MDHHS Guidance for Responding to Temperature Excursions

Important reminders regarding temperature excursions:

- ANY out-of-range temperature is considered an excursion and requires immediate action
- Providers are responsible to follow up on excursions, and Vaccines for Children (VFC) providers must notify their Local Health Department (LHD)
- If you are not confident in identifying or responding to an excursion, contact your LHD for assistance
- Do not use vaccine exposed to out-of-range temperatures until you have received guidance from the vaccine manufacturer and documented that guidance, or the LHD has determined that it is safe for use
- Each event is unique; the manufacturer recommendations during an excursion are based on existing stability data and cannot be applied to future events that seem to be similar
 - Every excursion requires appropriate notification and follow up to ensure vaccine viability determinations are made

If any temperature is out of range, follow these steps: Identify and Notify

- 1. Stop vaccinating with any vaccine that may have experienced an excursion
- 2. Do not discard vaccine(s), notify all staff by placing exposed vaccine in a separate storage container within the unit and label "DO NOT USE"
- 3. Store the vaccine in question at the manufacturer's recommended temperature while conducting the investigation on its viability
- 4. Notify your clinic's Primary/Backup Vaccine Coordinator and/or supervisor
- 5. Implement immediate corrective action (shut door if left open, resupply power, etc.)

Download, Evaluate, and Document Details of Event

- 6. Download the data logger and review all the data; prepare this information to share with each vaccine manufacturer and the LHD (the manufacturer will utilize the data and look at the cumulative exposure time/temperatures when determining vaccine viability)
- 7. Document all details of the event; VFC providers must notify their LHD and provide temperature excursion data if VFC stock is involved
- 8. If unit is not stabilizing, implement Emergency Plan for transport to backup location/unit; utilize CDC's guidance when packing for emergency transport, and always transport with data loggers
 - Ensure appropriate transport; see MDHHS Guidance on Vaccine Transport
 - For packing refrigerated vaccine in an emergency, see <u>CDC Guidance on Packing Vaccines for Transport During Emergencies</u>
 - Print and utilize <u>Transport Temperature Logs</u>

Contact Manufacturers and LHD

9. Contact every vaccine manufacturer for each vaccine in question to obtain a decision on vaccine stability (the vaccine manufacturers will request excursion temperatures, time, vaccines, etc.). Some manufacturers may have you fill out the report online. Always request a copy of your conversation with the manufacturer.

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10. Contact the LHD and provide all documentation, including manufacturer reports—details for vaccine losses can be reviewed in the Michigan VFC Provider Manual in section 8 under VFC Loss Policy at www.michigan.gov/vfc

Manufacturer Contact Information:

Dynavax: 1-844-375-4728

• GlaxoSmithKline: 1-888-825-5249 or

www.gskusmedicalaffairs.com

Merck: 1-800-672-6372Moderna: 1-866-663-3762

 Novavax: 1-844-668-2829Pfizer: 1-800-438-1985

 Sanofi Pasteur: 1-800-822-2463 or www.sanofiusmedicalinformation.com

• Segirus: 1-855-358-8966

Digital Data Logger Reminders:

• Check device calibration, and see if it may be due for recalibration or replacement

- Keep extra batteries on hand, and have a backup digital data logger available in case of malfunction or need of calibration
- All data logger requirements are outlined in the Michigan VFC Provider Manual, www.michigan.gov/vfc, under "Temperature Monitoring Devices"

Refer to These Resources for More Information:

- CDC Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- MDHHS guidance for storage and handling can be found at: www.michigan.gov/vaccinequicklooks
- Michigan VFC Provider Manual: www.michigan.gov/vfc
- Your Local Health Department VFC Contact

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